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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,159

01/14/2004

Barry N. Gellman

99-0033US2

3539

27774 7590 08/18/2009

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EXAMINER

SHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

08/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/757,159	Applicant(s) GELLMAN, BARRY N.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18, 20, 22, 23, 26-28 and 30-38 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 33-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18, 20, 22, 23, 26, 28, 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 17, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz-Feldman (US Patent No. 5,501,371). Schwartz-Feldman discloses a delivery system comprising an injector system coupled to a driving system, the injector system comprising: a housing (28) defining a lumen (22) and having an output end (near 36) and a driving system connection end (near 40); the lumen comprising a proximal portion (near 28) and a distal portion (near 86) and the inner diameter of the proximal portion being substantially larger than the inner diameter of the distal portion (the inner diameter at 28 is clearly larger than the inner diameter of the tapered portion of the distal end of the lumen at 40); a needle assembly (84) coupled to the output end of the housing (coupled at 36) for coupling to a needle; and a mixing member (Fig. 1, 26; col. 3, lines 36-37 disclose that the mixing means of the device is comprised of both element 100 and element 102) extending through the lumen from the driving system connection end to at least a portion of the needle assembly (Fig. 1 discloses that the needle assembly connects at 36 and Fig. 1 also discloses that end portion 140a of the mixing member extends into the needle assembly. Please note that

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portion 36 of the needle assembly is just as much a portion of the needle as is disclosed in Applicant's Figure 1. In Applicant's Fig. 1, the mixing member extends into the larger diameter portion of the needle but not the tapered portion. Fig. 1 of Schwartz-Feldman similarly discloses that the mixing member portion 140a extends into the larger diameter portion of the needle. As disclosed above, col. 3, lines 36-37 disclose that the mixing member is comprised of both 100 and 102 and as disclosed in Fig. 3, the distal end of 102 includes 130, which is therefore also part of the mixing member as it is an integrally formed part of 102. Also, portions 100 and 102 are interconnected as seen in Figs. 1 and 6, in which the blades 108a, 108b and 108c extend through slots 132a, b and c of element 102. Therefore any rotation of the blades 108 is thereby transmitted to element 102 because of the connection, thus end portion 130 rotates with the rotation of elements 100 and 102. This is further disclosed by col. 4, lines 33-41 in which Schwartz-Feldman discloses that the blades 108 are in an intermediate position, labeled as 108a', b' and c', which is disclosed in Fig. 6, which further clearly discloses that the blades extend through the slits 132 thereby allowing the rotation connection between elements 100 and 102. Thus the distal end 130 rotates within the needle assembly as well.), the mixing member being rotatable within the lumen in both the proximal portion and the distal portion (Figs. 1-8 disclose that the mixing member rotates within both these portions); and the driving system (50; col. 4, lines 12-14 disclose that 50 is the member that does the driving and is therefore the driving system) comprises: a drive mechanism (50); an actuator (56) coupled to the drive mechanism to actuate the drive mechanism (56 are the flanges which the user would grip in order to actuate the drive

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mechanism 50); and a rotatable interfacing member (interfacing member is made of ribs 66a, 66b, 66c and 66d which are located on the inner surface of 62, since 62 rotates, ribs 66a-66d rotate as well and these couple to the notches 110a, 110b, 110c and 110d on the mixing member which cause the mixing member to rotate (col. 3, lines 40-43) coupled to the drive mechanism for coupling the mixing member to rotate the mixing member when the interfacing member is driven by the drive mechanism (col. 3, lines 40-43), wherein the mixing member is rotatable in the needle assembly and the lumen (Fig. 1 discloses that the mixing member 100 rotates within the lumen 22 as well as within the needle assembly, as end portion 130 of the mixing member extends within the needle assembly in Fig. 1, where the end portion of the needle assembly that connects to the housing is at 36. (Fig. 1 discloses that the needle assembly connects at 36 and Fig. 1 also discloses that end portion 140a of the mixing member extends into the needle assembly. As disclosed above, col. 3, lines 36-37 disclose that the mixing member is comprised of both 100 and 102 and as disclosed in Fig. 3, the distal end of 102 includes 130, which is therefore also part of the mixing member as it is an integrally formed part of 102. Also, portions 100 and 102 are interconnected as seen in Figs. 1 and 6, in which the blades 108a, 108b and 108c extend through slots 132a, b and c of element 102. Therefore any rotation of the blades 108 is thereby transmitted to element 102 because of the connection, thus end portion 130 rotates with the rotation of elements 100 and 102. This is further disclosed by col. 4, lines 33-41 in which Schwartz-Feldman discloses that the blades 108 are in an intermediate position, labeled as 108a', b' and c', which is disclosed in Fig. 6, which further clearly discloses that the

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blades extend through the slits 132 thereby allowing the rotation connection between elements 100 and 102. Thus the distal end 130 rotates within the needle assembly as well.) and wherein mixing occurs in the needle assembly (since 140a rotates when blades 108 rotate, when the system is in positions as seen in Figs. 8 and 9 which allows material to enter portion 36 of the needle assembly, if blades are rotated during this time, portions 140a of the mixing member will also rotate and will thereby "mix" the material. Clearly elements 140a are still capable of mixing material within the needle assembly portion 36 when the system is in a position in which material is present in portion 36.).

In reference to claim 17, Schwartz-Feldman discloses that the driving system is capable of coupling to an injector system (Fig. 1), the injector system comprising a tubular member (28) and a mixing member (100) extending through the tubular member (Fig. 1).

In reference to claims 31 and 32, Schwartz-Feldman discloses that the injector system comprises an injectable material comprising a shear-sensitive injectable material (please note that this component is part of the injector system which is part of the intended use phrasing of the claim and therefore the driving system merely has to be capable of use with it, which it is. Also, the reference discloses that the device is used to mix dental impression material which changes viscosity as it is mixed and is then subjected to shear forces when being injected through the needle, which therefore meets Applicant's definition of a shear sensitive material).

Claims 18, 20, 22, 23 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz-Feldman (US Patent No. 5,501,371). Schwartz-Feldman discloses a coupling system for use with a tube of a syringe comprising: a housing (28) for coupling to the tube of the syringe, said syringe comprising a needle assembly coupled to an output end of the tube (needle assembly is 36/84); a drive mechanism disposed within the housing (50; col. 4, lines 12-14 disclose that 50 is the member that does the driving and is therefore the driving system); a mixing member for coupling to the drive mechanism (Fig. 1, 26; col. 3, lines 36-37 disclose that the mixing means of the device is comprised of both element 100 and element 102), the mixing member extending into the tube of the syringe and being rotatable within the tube of the syringe in both the proximal portion and the distal portion and at least a portion of the needle assembly to mix and deliver an injectable from the tube of the syringe (Fig. 1 discloses that the mixing member 100 rotates within the lumen 22 as well as within the needle assembly, as end portion 130 of the mixing member extends within the needle assembly in Fig. 1, where the end portion of the needle assembly that connects to the housing is at 36. (Fig. 1 discloses that the needle assembly connects at 36 and Fig. 1 also discloses that end portion 140a of the mixing member extends into the needle assembly. As disclosed above, col. 3, lines 36-37 disclose that the mixing member is comprised of both 100 and 102 and as disclosed in Fig. 3, the distal end of 102 includes 130, which is therefore also part of the mixing member as it is an integrally formed part of 102. Also, portions 100 and 102 are interconnected as seen in Figs. 1 and 6, in

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which the blades 108a, 108b and 108c extend through slots 132a, b and c of element 102. Therefore any rotation of the blades 108 is thereby transmitted to element 102 because of the connection, thus end portion 130 rotates with the rotation of elements 100 and 102. This is further disclosed by col. 4, lines 33-41 in which Schwartz-Feldman discloses that the blades 108 are in an intermediate position, labeled as 108a', b' and c', which is disclosed in Fig. 6, which further clearly discloses that the blades extend through the slits 132 thereby allowing the rotation connection between elements 100 and 102. Thus the distal end 130 rotates within the needle assembly as well.); and an actuator coupled to the drive mechanism to actuate the drive mechanism and thereby cause rotation of the mixing member (56 are the flanges which the user would grip in order to actuate the drive mechanism 50), and mixing occurs in the needle assembly and the tube (since 140a rotates when blades 108 rotate, when the system is in positions as seen in Figs. 8 and 9 which allows material to enter portion 36 of the needle assembly, if blades are rotated during this time, portions 140a of the mixing member will also rotate and will thereby "mix" the material. Clearly elements 140a are still capable of mixing material within the needle assembly portion 36 when the system is in a position in which material is present in portion 36.).

In reference to claim 20, Schwartz-Feldman discloses that the housing comprises a mating portion, the mating portion being capable of mating with the tube of the syringe (Fig. 1).

In reference to claim 22, Schwartz-Feldman discloses that the tube of the syringe comprises an injectable material (abstract).

In reference to claim 23, Schwartz-Feldman discloses that the housing comprises finger grips (Fig. 1).

In reference to claim 30, Schwartz-Feldman discloses that the injectable material comprises a shear-sensitive injectable material (col. 11, lines 12-18 disclose that the device is used to mix dental impression material which changes viscosity as it is mixed and is then subjected to shear forces when being injected through the needle, which therefore meets Applicant's definition of a shear sensitive material).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz-Feldman (US Patent No. 5,501,371) in view of Critchlow et al. (US

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2003/0171712). Schwartz-Feldman discloses the device substantially as claimed except for a low torque motor, a battery or a switch. Critchlow, however, discloses a hand-held syringe (Fig. 9) with a high speed, low torque motor (paragraph [0053]), that the motor is coupled to a battery as an energy source (paragraph [0046]) and that the actuator comprises a switch (paragraph [0128]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hicks with the specific motor, energy source and switch, as taught by Critchlow, in order to provide an injector system that is powerful enough to mix and inject such viscous material, as well as be hand-held and portable.

Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz-Feldman (US Patent No. 5,501,371) in view of Barker et al. (US Patent No. 6,033,105). Schwartz-Feldman discloses the device substantially as claimed except for the mixing member comprising a helical element. Barker, however, discloses a similar mixing device in which the mixing member comprises a helical element (Fig. 2, 30 for example). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Schwartz-Feldman with the helical element as taught by Barker, in order to provide a mixing member that both mixes the material and guides the material downwards toward the needle for subsequent injection. Furthermore, changing the mixing member to a helical member would require only a

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change in shape which is generally recognized as being within the level of ordinary skill in the art.

Response to Arguments

Applicant's arguments with respect to claims 18, 20, 22, 23, 28 and 30 have been considered but are moot in view of the new ground(s) of rejection.

With respect to Applicant's arguments in regards to the rejection of claims 11, 17, 31 and 32 under Schwart-Feldman, it is still the examiner's position that the claims as currently worded are anticipated by the reference. Applicant argues that the mixing member does not extend into the tapered tip of the needle, however "tapered tip" is not in the claim language. Also, Applicant argues that mixing does not occur within the needle assembly, however, if the mixing assembly is rotated when in the position as depicted in Figs. 8 and 9 of Schwartz-Feldman, material would be present in portion 36 of the needle assembly, and any rotation imparted to 108 would also rotate 140 and therefore mixing would occur in portion 36 of the needle assembly. It is the examiner's position that the reference is capable of mixing within the needle assembly.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767